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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,215	02/25/2004	Hugh S. West JR.	14000.8.1.2	3044

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John M. Guynn
WORKMAN, NYDEGGER & SEELEY
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111

EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,215

Applicant(s)

WEST ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 11-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. (US Pat. 5,713,897).

Goble et al. disclose a suture pulley assembly (Fig. 1, ref. 80) comprising: a pulley wheel comprising first (Fig. 1, ref. 93) and second pulley plates, sized and positioned so as to define a pulley space therebetween. The second pulley plate can be considered to be plate 94 (Fig. 1) in conjunction with the wheel 97 (Fig. 1). The pulley space is the area between the first plate and the wheel 97. Attaching means (Fig. 7, ref. 95) for rotatably (column 8, lines 66-67 and column 9, lines 1-3) attaching the pulley wheel to an adjustable tension applicator (Fig. 1, ref. 20) of the graft tensioning device; and biasing means (Fig. 7, ref. 100) for biasing at least one of the pulley plates toward the other of the pulley plates. The attachment means comprising a post (Fig. 7, ref. 95) that passes through a central recess of each pulley plate and that is attached at a first end to the adjustable tension applicator of the graft tensioning device. The end of the post that is furthest from the pointer body 98 (Fig. 7) can be considered to be the first end of the post. The post is fixedly attached to the adjustable tension applicator. The post further comprises a flange (Fig. 7, ref. 99) at a second end opposite the first end and adjacent to one of the pulley plates (Fig. 7), the flange overlapping at least a portion

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of an outer surface of the pulley plate adjacent to the flange (Fig. 7). The biasing means comprise a spring (Fig. 7, ref 100). The spring being positioned between one of the pulley plates and the adjustable tension applicator of the graft tensioning device (Fig. 8). The first and second pulley plates can spread apart relative to each other so as to selectively define a larger pulley space in response to tying a half knot within one or more suture strands and then clamp the half knot while a remaining portion of the suture knot is tied. The first and second pulley plates can spread apart relative to each other so as to selectively define a larger pulley space in response to inserting a suture having a knot into the pulley space. The first and second pulley plates are capable of spreading apart. The spring is attached to plate 93 and wheel 97 (column 9, lines 16-18), creating a tension between those plates, which would cause a deformation of the plates towards each other. Inserting an object, such as a suture, between plate 93 and wheel 97 would create a force that would push the plates away from each other temporarily, until the object is removed.

Goble et al. further disclose a graft tensioning device (Fig. 1) for use in joint repair surgery, comprising: a suture pulley assembly (Fig. 1, ref. 80); at least one adjustable tension applicator (Fig. 1, ref. 20) to which the suture pulley assembly is rotatably (column 8, lines 66-67 and column 9, lines 1-3) attached and which is configured to apply a desired tensile load to a looped suture attached to free ends of a looped tissue graft, the suture pulley assembly equalizing a tensile load applied by the adjustable tension applicator to each side of the looped suture.

Goble et al. further disclose, in a graft tensioning device for use in joint repair surgery, a suture pulley assembly comprising: a pulley wheel comprising first (Fig. 1, ref. 93) and second pulley plates sized and positioned so as to define a pulley space therebetween. The second pulley plate can be considered to be plate 94 (Fig. 1) in conjunction with the wheel 97 (Fig. 1). The pulley space is the area between the first plate and the wheel 97. Goble et al. further discloses a post (Fig. 7, ref. 95) attached at a first end to an adjustable tension applicator of the tensioning device. The post passes through a central recess of each of the first and second pulley plates so as to rotatably (column 8, lines 66-67 and column 9, lines 1-3) attach the pulley wheel to the adjustable tension applicator (Fig. 1, ref. 20), and a spring (Fig. 7, ref. 100) positioned relative to at least one of the first and second pulley plates so as to bias at least one of the pulley plates toward the other of the pulley plates. The first and second pulley plates have inner surfaces that define the pulley space. The inner surfaces are the surfaces of the plate that are facing each other. At least a portion of the inner surfaces of the first and second pulley plates being angled so that at least a portion of the pulley space has decreasing width from an outer perimeter of the pulley plates toward a center of the pulley wheel. Considering the second pulley plate to be plate 94 (Fig. 1) in conjunction with the wheel 97 (Fig. 1), then the width of the pulley space is wider near the top of the pulley wheel, where the wheel 97 (Fig. 1) does not extend, than it is where the wheel 97 (Fig. 1) does extend. A portion of the pulley space nearest the center of the pulley wheel has a constant width. The pulley space nearest the center of the pulley wheel has a constant width, because wheel 97 (Fig. 1) and the first pulley plate have a constant

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width and are separated by a constant distance (Fig. 4). The first and second pulley plates are capable of spreading apart so as to temporarily define a larger pulley space in response to inserting a suture having a knot or half knot into the pulley space. The spring is attached to plate 93 and wheel 97 (column 9, lines 16-18), creating a tension between those plates, which would cause a deformation of the plates towards each other. Inserting an object, such as a suture, between plate 93 and wheel 97 would create a force that would push the plates away from each other temporarily, until the object is removed. The post is fixedly attached to the adjustable tension applicator. The post further comprises a flange (Fig. 7, ref. 99) at a second end opposite the first end and adjacent to one of the pulley plates, the flange overlapping at least a portion of an outer surface of the pulley plate adjacent to the flange (Fig. 7). The spring being positioned between one of the pulley plates and the adjustable tension applicator of the graft tensioning device (Fig. 8). The spring is positioned between one of the pulley plates and the flange of the post (Fig. 8). The device further comprises a sleeve (Fig. 7, ref. 86a) disposed around at least a portion of the post between the post and an inner edge of each pulley plate defining the central recess. The definition of "disposed," according to the American Heritage Dictionary of the English Language, Fourth Edition is "to place or set in a particular order; arrange." The sleeve is placed around or near to the post (Fig. 7). The spring is disposed around a portion of the sleeve. The spring is placed around or near to a portion of the sleeve. The device further comprises a washer (Fig. 8, ref. 26) disposed between the spring and the adjustable tension applicator of the graft tensioning device.

Goble et al. further disclose a graft tensioning device for use in joint repair surgery, comprising: at least one adjustable tension applicator (Fig. 1, ref. 20) configured to apply a desired tensile load to a looped suture attached to free ends of a looped tissue graft; and a suture pulley assembly (Fig. 1, ref. 80) rotatably (column 8, lines 66-67 and column 9, lines 1-3) attached to the adjustable tension applicator so as to equalize a tensile load applied by the adjustable tension applicator to each side of the looped suture, the suture pulley assembly comprising: a pulley wheel comprising first (Fig. 1, ref. 93) and second pulley plates sized and positioned so as to define a pulley space therebetween. The second pulley plate can be considered to be plate 94 (Fig. 1) in conjunction with the wheel 97 (Fig. 1). Goble et al. further disclose a post (Fig. 7, ref. 95) attached at a first end to an adjustable tension applicator of the graft tensioning device, the post passing through a central recess of each of the first and second pulley plates so as to rotatably attach the pulley wheel to the adjustable tension applicator; and a spring (Fig. 7, ref. 100) positioned relative to at least one of the first and second pulley plates so as to bias at least one of the pulley plates toward the other of the pulley plates.

With regard to statements of intended use and other functional statements (e.g. ...so as to equalize a tensile load applied by said adjustable tension applicator...), they do not impose any structural limitations on the claims distinguishable over the graft tensioning device of Goble et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the

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reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US Pat. 5,713,897) in view of Lewis et al. (US. Pat. 4,950,271).

Goble et al. disclose the claimed invention except for the graft tensioning device comprising two independently adjustable tension applicators and a separate suture pulley rotatably attached to each of the two independently adjustable tension applicators.

Lewis et al. disclose a graft tensioning device comprising two independently adjustable tension applicators (Fig. 2, ref. 62) and a separate suture pulley rotatably attached to each of the two independently adjustable tension applicators (Fig. 2, ref. 57), in order to apply different loads to a multiple strand or segment ligament graft and

to prescribe the load shared between the segments, which aids in proper joint reconstruction (column 1, lines 66-68 and column 2, lines 1-7).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the graft tensioning device of Goble et al. with two independently adjustable tension applicators and a separate suture pulley rotatably attached to each of the two independently adjustable tension applicators, in order to permit one to use the graft tensioning device of Goble et al. to apply different loads to a multiple strand or segment ligament graft and to prescribe the load shared between the segments, which aids in proper joint reconstruction (column 1, lines 66-68 and column 2, lines 1-7).

Response to Arguments

Applicant's arguments filed 09/08/2006 have been fully considered but they are not persuasive.

Applicant argues that the device of Goble et al. does not provide a rotatable suture wheel. The definition of rotate, according to the Merriam-Webster Online Dictionary, is "to cause to turn or move about an axis or a center." The wheel that that examiner has specified comprises first (Fig. 1, ref. 93) and second (Fig. 1 ref. 94, in conjunction with ref. 97) pulley plates. Any portion of the device of Goble et al., including the wheel, is capable of being rotated, or is rotatable, since any portion of the device is capable of being picked up by a user and spun about an axis. The portion that the examiner has specified as comprising the wheel (Fig. 1, ref. 93) (Fig. 1 ref. 94, in conjunction with ref. 97) has a further ability to rotate as the portion of ref. 97 can rotate

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independently of the main body of the device (column 9, lines 66-67 and column 9, lines 1-3).

Applicant further argues that the device of Goble is not capable of accommodating looped sutures of various cross sectional width, and that the plates of Gobel et al. cannot move apart in response to a greater width of a different sized knot. Applicant further argues that no such structure and functionality are taught or suggested in the prior art cited. With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Goble et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The device of Goble is capable of accommodating looped sutures of various cross sectional width, since looped sutures with different widths can be placed into the pulley space (the area between the first plate and the wheel 97). Furthermore, the plates can move apart in response to a greater width of a different sized knot. The spring is attached to plate 93 and wheel 97 (column 9, lines 16-18), creating a tension between those plates, which would cause a deformation of the plates towards each

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other. Inserting an object, such as a suture, between plate 93 and wheel 97 would create a force that would push the plates away from each other temporarily, until the object is removed. Furthermore, the plate is capable of equalizing tension between each side of a looped suture through rotation of the pulley wheel. If the looped suture is placed along the wheel so that each side of the suture is placed symmetrically about the wheel, when the wheel is rotated it would be possible to place a symmetrical force on each side of the looped suture, which would lead to equal tensions on either side of the suture.

In response to Applicant's argument that the plates are not rotatable relative to other portions of the device, the limitations on which the Applicant relies are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not. The limitations in the claims state that the pulley wheel is rotatable, but not that the pulley wheel is rotatable relative to any other portion of the device.

Applicant further argues that the pulley space of Goble is not capable of having a looped suture strand inserted in it. The examiner respectfully disagrees. There exists enough space in the pulley space to include the spring (Fig. 7, ref. 101). The spring does not extend and cover the entire area in between the plates (Fig. 7), nor does the spring extend around the entire circumference of the pulley space, which would effectively block entrance of a looped suture, but the spring resides between the circumference of the pulley space (near ref. 93) and the center of the plate near reference 95. The looped suture could be placed in the area between the outer circumference of the plates (near ref. 93) and the center of the plates (near ref. 95).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

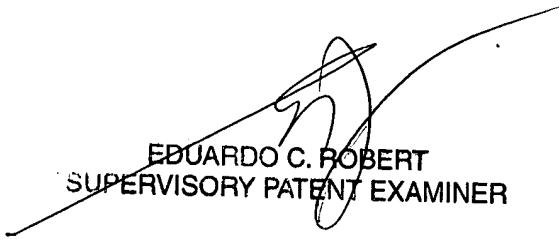
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER